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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,734	09/11/2000	Winfried Edelmann	AHN-001DV1	9039

959                      7590                      12/31/2002

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
1651	//

1651

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/658,734

Applicant(s)

EDELMANN ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 09 October 2002.
- 2a)  This action is FINAL.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 13,14 and 23-32 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 3-14,23-32 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All   b)  Some \*   c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other:

### DETAILED ACTION

Applicant's amendment has been received and entered into the case. Claim 22 has been cancelled and claims 30 – 32 have been added. Claims 13 – 14 and 23 – 32 are pending and have been considered on the merits. All arguments have been considered on the merits.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13 – 14 and 23 – 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13, 30, 31, 32 and their dependents are drawn to a method for identifying a contraceptive or compound which modulates meiosis, however are rendered vague and indefinite for reciting “said compound” in step d because it is unclear if “said compound” is referring to the test compound of steps a and b, or the selected compound of step c. Applicant may prefer to insert the word “selected” between “said” and “compound” of step d, to more clearly identify which compound is identified as the compounds useful as a contraceptive or modulator of meiosis.

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Claim 30 is rendered vague and indefinite for reciting "modulates" in step c, because it is unclear what activity must occur for the compound to qualify as a contraceptive. For example, does the compound inhibit, stimulate, destroy, or deactivate MSH5?

*Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 31 – 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishel in view of Winand et al. (1998)

Applicant claims a method for identifying a compound which modulates meiosis in a cell, the method comprising a) contacting MSH5 with a test compound, and b) determining the

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activity of MSH5 in the presence and absence of the test compound, c) selecting the compound which modulates MSH5 activity, and d) identify the selected compound as a compound that modulates meiosis in a cell. Applicant additionally claims the method wherein a cell expressing MSH5 is contacted with a test compound.

Fishel teaches a method for determining if a composition (test compound) affects (or modulates) expression of a gene encoding a MutS homolog (MSH) (col.9 line 10-15) wherein the MutS homolog may be MSH5 (col.4 line 35-40). The method comprises administering the test composition (or compound) to a cell containing the MutS homolog (or MSH5) and a cell which does not contain the MutS homolog followed by observing phenotypic effects on the cells to determine if the compound effects (or modulates) MutS homolog activity (col.9 line 29-45).

Fishel does not teach the method wherein the test compound that modulates MSH5 is useful for modulating meiosis. However, Winand teaches that MSH5 is required in normal meiotic crossing over (abstract, p.69 right column) and encodes proteins which function in meiotic cells (p.69, right column). Moreover, at the time of the claimed invention, it was known in the art that MSH5 plays a modulating role in meiosis. Therefore, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to identify meiosis-modulating-compounds by identifying compounds which modulate MSH5. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Winand to use the methods of Fishel for identifying compounds which modulate MSH5, with a reasonable expectation for successfully identifying compounds which modulate meiosis.

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Applicant argues that the references do not teach a relationship between MSH5 and meiosis modulation.

However, this argument fails to persuade because as disclosed by Winand, it was known in the art that MSH5 plays a crucial role in meiosis, as stated above.

### *Conclusion*

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad  
December 26, 2002

  
LEON B. LANKFORD, JR.  
PRIMARY EXAMINER